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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.               | CONFIRMATION NO. |
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| 08/786,937   | 01/22/1997  | PHILIPPE BOUCHARD    | 235299/96001                      | 5859             |
| 909  | 7590        | 09/13/2006           |                                   |                  |
| PILLSBURY WINTHROP SHAW PITTMAN, LLP<br>P.O. BOX 10500<br>MCLEAN, VA 22102 |             |                      | EXAMINER<br>BORGEEST, CHRISTINA M |                  |
|  |             |                      | ART UNIT                          | PAPER NUMBER     |
|  |             |                      | 1649                              |                  |

DATE MAILED: 09/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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|                              |                                       |  |  |
|------------------------------|---------------------------------------|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>08/786,937  | <b>Applicant(s)</b><br>BOUCHARD ET AL. |  |
|                              | <b>Examiner</b><br>Christina Borgeest | <b>Art Unit</b><br>1649                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 38-40, 44-53, 56-63, 65, 67-75, 78-84, 86-92, 94-100, 102-108, 110-116 and 118-128 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Continuation of Disposition of Claims: Claims pending in the application are 38-40,44-53,56-63,65,67-75,78-84,86-92,94-100,102-108,110-116 and 118-128.

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## **DETAILED ACTION**

### ***Formal Matters***

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1649, Examiner Christina Borgeest, Ph.D.

The most recent claim set was submitted 29 November 2005. Claims 38, 51, 61, 73, 83, 92 and 115 are amended. Claims 1-37, 41, 43, 54, 55, 64, 66, 73, 76, 77, 85, 93, 101, 109, 117 are cancelled. Claims 38-40, 44-53, 56-63, 65, 67-75, 78-84, 86-92, 94-100, 102-108, 110-116 and 118-128 are pending and under review.

A request for an extension of time was filed 23 March 2006. As indicated in the interview summary of 6 July 2006, on further consideration, the finality of the previous Office action (mailed 23 September 2005) is hereby withdrawn. It is noted that a Notice of Appeal has been filed. Applicants can reuest a refund for the associated fees or leave it as credit for future appeals.

### ***Claim Rejections - 35 USC § 112, first paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 38-40, 44-50, 61-63, 65, 67-72, 83-84, 86-91, 99-100, 102-107, 115-116 and 118-128 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the claimed methods comprising (a)

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administration of hMG, and (b) administering Cetorelix does not reasonably provide enablement for the administration of "exogenous gonadotropins" and "GnRH antagonists" as broadly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." (See *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 Fed. Cir. 1988) These factors include, but are not limited to: (a) the breadth of the claims; (b) the nature of the invention; (c) the state of the prior art; (d) the level of one of ordinary skill; (e) the level of predictability in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

First, the recitation of "gonadotropins" broadens the scope of the claims beyond what is enabled by the disclosure. Gonadotropins are defined protein hormones secreted by the pituitary gonadotrope cells in vertebrates and include follicle stimulating hormone (FSH), luteinizing hormone (LH), and human chorionic gonadotropin (hCG) and thyroid stimulating hormone (TSH). Neither the specification, nor the literature at the time the application was filed suggested that TSH, LH alone or hCG could be used to induce follicle growth, but rather hMG, which is a mixture of FSH and LH, is disclosed in the specification as capable of stimulating follicle growth. Later, the literature teaches

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that recombinant FSH could be used to stimulate follicle growth. Nevertheless the breadth of administering "gonadotropins" as broadly claimed to induce follicle growth is not supported by the specification or the literature.

Second, the recitation of the administration of "LHRH antagonist" broadens the scope. In 2004, eight years after the filing of the instant application, only two LHRH antagonists were commercially available for prevention of premature LH surges in ovarian stimulation for ART, namely Cetrorelix and Ganirelix (see Griesinger et al., *Drugs*. 2004; 64: 563 – 575; p. 565, right column, 1<sup>st</sup> paragraph). The same article discloses that the first antagonistic analogs of GnRH were ineffective because of the "strong lipophilic properties...resulting in low solubility and the tendency to form gels in aqueous solutions." (See p. 565, left column, last paragraph). The claims encompass non-functioning LHRH antagonists as well as those that are yet to be discovered.

Due to the large quantity of experimentation necessary to determine all the functioning antagonistic analogs of LHRH, the lack of direction/guidance presented in the specification regarding and the absence of working examples directed to the same as well as the ability of gonadotropins as broadly claimed to stimulate ovarian follicle growth, the complex nature of the invention, the contradictory state of the prior art (see for instance, Griesinger et al. regarding functioning LHRH antagonists), and the breadth of the claims which fail to recite limitations to "gonadotropins" and "LHRH antagonists", undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

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In addition, claims 83 – 128 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." (See *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 Fed. Cir. 1988) These factors include, but are not limited to: (a) the breadth of the claims; (b) the nature of the invention; (c) the state of the prior art; (d) the level of one of ordinary skill; (e) the level of predictability in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The claims recite methods for obtaining the production of a fertilizable oocyte within a program of COS/ART (claims 83 – 98, 115 – 128) or an improved method for obtaining the production of a fertilizable oocyte (claims 99 – 114), comprising (a) administering an exogenous gonadotropin to induce follicle growth (b) administering a LHRH antagonist to prevent a premature LH surge, wherein the LHRH antagonist is administered in a dosage regimen of daily doses of 0.25 mg/day for multiple days. The issues of breadth raised by the recitation of "gonadotropin" and "LHRH antagonist" are discussed above under the scope of enablement rejection and apply here as well. The

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specification states that a total of 235 patients were treated and that “[n]o premature LH surge was seen in patients undergoing COS/ART treated with either multiple doses of 0.25 mg or higher or a single dose of 3 mg or higher,” (see p. 6, last paragraph), however, Table I (p. 7 of the specification) shows that the dose actually used in the clinical trial was 0.5 mg, not 0.25 mg, twice the amount that is claimed, thus the 0.25 mg dose was not tested as of filing. While it is not necessary for Applicants to have working examples for all the embodiments of their claims (see, for example, 2164.01(c) of the MPEP: “An applicant need not have actually reduced the invention to practice prior to filing.”) However, the same section of the MPEP also states: “Lack of a working example, however, is a factor to be considered, especially in a case involving an unpredictable and undeveloped art.” Assisted reproduction is a highly unpredictable area and the level of success in the art is still quite low. (See Diedrich et al. Hum Reprod. 1994; 9: 788-791—cited on Applicants 1449 form 22 June 1998—report only a 14 – 17% pregnancy rate at p. 788, right column, Table I).

In the absence of a guidance in the specification, the literature can provide support for the claims. However, the literature suggests that the 0.25 mg/day dose is associated with a high incidence of premature LH surges and adverse cycle outcome (see Tavanioutou et al. Reprod. BioMed Online. 2003. 6: 421 – 426 and Engel et al. (Human Reprod. 2002. 17: 2022 – 2026). Specifically, Tavanioutou et al. teach “[h]igh LH concentrations have been postulated to be responsible for low fertilization rates in IVF and for increased embryonic loss.” (See abstract and p. 422, left column, 1<sup>st</sup> paragraph). Engel et al. recommend that increasing the daily Cetorelix dose from 0.25

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to 0.5 mg might decrease the number of premature LH surges (see abstract and p. 2025, left column, 4<sup>th</sup> paragraph). Finally, Felberbaum et al. (Journal of Assisted Reproduction and Genetics. 1996. 13: 216 – 222), published at the time of filing of the instant application, state in their conclusion (p. 221, left column, last paragraph to right column 1<sup>st</sup> paragraph) that the minimal effective dosage of Cetrorelix per day remains undefined. Based on the teachings in the literature, the 0.25 mg dose of Cetrorelix is not high enough to block premature LH surges and may lead to low fertilization rates, thus the goals of obtaining the production of a fertilizable oocyte within a program of COS/ART (claims 83 – 98, 115 – 128) or an improved method for obtaining the production of a fertilizable oocyte (claims 99 – 114) are not enabled by the prior art. Thus the goals of ***obtaining the production of a fertilizable oocyte*** within a program of COS/ART (claims 83 – 98, 115 – 128) or an ***improved method*** for obtaining the production of a fertilizable oocyte (claims 99 – 114) as recited in the claims comprising administering exogenous gonadotropin followed by daily doses of 0.25 mg/day for multiple days is not enabled.

Due to the breadth of the recitations of “gonadotropins” and LHRH antagonists, the lack of direction/guidance presented in the specification regarding the efficacy of the 0.25 mg Cetrorelix dose for obtaining a fertilizable oocyte, the absence of working examples directed to the same, the level of skill in the art, the complex nature of the invention and the contradictory state of the prior art (see Tavanioutou et al. and Engel et al.), the unpredictability of the ART field, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 38-39, 42, 45, 46, 48, 49, 50, 51, 52, 56, 57, 58, 60, 61, 62, 65, 67, 68, 69, 71, 72, 73, 74, 78, 79, 80, 82 are rejected under 35 U.S.C. 102(b) as being anticipated by Olivennes et al. (Fertil Steril. 1994. 62: 468-476—cited on Applicants 1449 form submitted 3 August 2004).

The claims are drawn to a method for obtaining the production of a fertilizable oocyte within a program of controlled ovarian stimulation for assisted reproduction techniques (COS/ART) comprising: (a) administering an exogenous gonadotropin to induce follicle growth, and (b) administering a luteinizing hormone releasing hormone (LHRH) antagonist to prevent a premature LH surge, wherein the LHRH antagonist is administered in a single or dual dosage regimen of 1 to 10 mg per dose beginning on menstruation cycle day 1 to 9 and wherein follicular growth occurs in the absence of an LH surge, a fertilizable oocyte is produced, ovulation occurs between day 9 and 20 of the menstruation cycle, and the LHRH antagonist is sufficient to suppress LH, while FSH secretion is maintained at a natural level and individual estrogen development is not affected, wherein the dosage of LHRH antagonist is in the range of 2-6 mg per dose and is administered by subcutaneous injection, wherein the LHRH antagonist is administered starting cycle day – 8 or 6 – 10 and ovulation occurs between day 9 – 16 of the menstruation cycle or wherein ovulation occurs within 6.5 days following

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administration of a single or second dose of the LHRH antagonist, wherein ovulation occurs without the administration of a hormone or hormone agonist to induce ovulation, or wherein ovulation is induced by administering a hormone or hormone agonist to induce ovulation and the hormone or hormone agonist selected from the group consisting of native LH, recombinant LH, an LHRH agonist and hCG, wherein the LHRH antagonist is Cetrorelix. Note that such phrases as "for obtaining the production of a fertilizable oocyte" or "an improved method" are treated as preambles, and though they are considered for the purposes of enablement, they are not given patentable weight with respect to the art.

Olivennes et al. teach a method comprising administration of exogenous gonadotropin (hMG) every day starting on day 2 of the cycle, followed by a single 5 mg subcutaneous dose of Cetrorelix (GnRH antagonist) between days 8 – 10 of the cycle when endogenous estradiol levels are optimal. A second dose follows 48 hours later if the triggering of ovulation was not achieved. Triggering of ovulation was achieved with the administration of 10,000 IU of hCG. (See p. 469, right column under Study Protocol and Figure 1 on p. 470 for a schematic of treatment regimen). The method steps recited in the claims are the same as those taught by Olivennes et al. The claims also recite purported effects of the treatment, such as "wherein follicular growth occurs in the absence of an LH surge, a fertilizable oocyte is produced, ovulation occurs between day 9 and 20 (or day 9 – 16) of the menstruation cycle, and the LHRH antagonist is sufficient to suppress LH, while FSH secretion is maintained at a natural level and individual estrogen development is not affected." Because Olivennes et al. teach the

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same method steps to the identical patient population (women undergoing ART), the effects that are recited in the claims would by necessity also be achieved by the method taught by Olivenness et al. Note MPEP 2112, I. "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition [or method] patentably new to the discoverer."

In addition, Applicants have made some arguments in their remarks filed 15 June 2005 that are directly applicable to the current rejection under 35 U.S.C. 102(b) and will be addressed here. Note that the current Examiner did not maintain the rejection under 35 U.S.C. 103(a) made by the previous Examiner, nor did the current Examiner make a new rejection under this statute. For this reason, the arguments made by Applicants' regarding the previous Examiner's rejection under 103(a) were not addressed because said arguments are moot since no obviousness type rejection was made.

Applicants argue at p. 15, 2<sup>nd</sup> and 3<sup>rd</sup>, p. 16, 1<sup>st</sup> and 2<sup>nd</sup> paragraphs and p. 17, 1<sup>st</sup> paragraphs that Olivenness et al. teach the additional step of monitoring estradiol levels and performing ultrasound to identify the number of maturing follicles, thus the first dose of Cetrorelix could be injected to early or to late and Olivenness et al. do not anticipate Applicants' streamlined methods.

Applicants argue at p. 16, 3<sup>rd</sup> paragraph that Applicants' invention does not require the steps of drawing blood and performing ultrasounds, and that the invention requires only a scheduling of either a single or dual dose regimen of LHRH antagonists

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between days 1 – 10 of the menstrual cycle in conjunction with administering exogenous gonadotropin to induce follicle growth.

Applicants argue at p. 16, 3<sup>rd</sup> paragraph that Applicants have unexpectedly determined that doses of an LHRH antagonist ranging from 1 – 10 mgs can be administered as early as day 1 and as late as day 10 of the menstrual cycle wherein the LH surge is prevented, FSH secretion is maintained at a natural level, which Applicants assert is different from the teachings of Oliveness et al. (Applicants point to p. 470).

These arguments have been fully considered but are not found persuasive for the following reasons. First, with regard to Applicants' argument that Oliveness et al. teach the additional step of monitoring estradiol levels and performing ultrasound to identify the number of maturing follicles, thus the first dose of Cetrorelix could be injected to early or to late and Oliveness et al. and do not anticipate Applicants' streamlined methods, it is noted that the features upon which Applicants rely in their arguments (i.e., not having to perform estradiol measurements and/or ultrasound the and that their invention requires **only** a scheduling of either a single or dual dose regimen of LHRH antagonists between days 1 – 10 of the menstrual cycle in conjunction with administering exogenous gonadotropin to induce follicle growth, **with no additional steps**) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Note also that the claims recite a method "comprising", thus the extra steps taught by Oliveness et al. are encompassed by the open language recited in the claims.

Second, with regard to the argument that that Applicants have unexpectedly determined that doses of an LHRH antagonist ranging from 1 – 10 mgs can be administered as early as day 1 and as late as day 10 of the menstrual cycle wherein the LH surge is prevented, FSH secretion is maintained at a natural level, which Applicants assert is different from the teachings of Oliveness et al. (Applicants point to p. 470, presumably to demonstrate that FSH levels are initially higher than normal), Applicants' method steps as recited in the claims are not clearly or explicitly distinguished over the prior art. Both Applicants and Oliveness and colleagues teach a method comprising administration of exogenous hMG each day starting on day 2 of the cycle, followed by a single 5 mg subcutaneous dose of Cetrorelix between days 8 – 10 wherein ovulation was achieved with the administration of 10,000 IU of hCG. Applicants' assert in the claims that the their methods maintain FSH secretion at a natural level, however, since the method steps in the claims are substantially the same as those taught by Oliveness et al., Applicants' assertion does not distinguish the claimed methods over those taught by Oliveness and colleagues.

Claims 38, 39, 40, 42, 44, 45, 46, 48, 49, 50, 51, 52, 53, 56, 57, 58, 60, 61, 62, 63, 65, 67, 68, 71, 72, 73, 74, 75, 78, 79, 80 and 82 are rejected under 35 U.S.C. 102(b) as being anticipated by Diedrich et al. Hum Reprod. 1994; 9: 788-791—cited on Applicants 1449 form 22 June 1998).

The claims are drawn to a method for obtaining the production of a fertilizable oocyte within a program of controlled ovarian stimulation for assisted reproduction

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techniques (COS/ART) comprising: (a) administering an exogenous gonadotropin to induce follicle growth, and (b) administering a luteinizing hormone releasing hormone (LHRH) antagonist to prevent a premature LH surge, wherein the LHRH antagonist is administered in a single or dual dosage regimen of 1 to 10 mg per dose beginning on menstruation cycle day 1 to 9 and wherein follicular growth occurs in the absence of an LH surge, a fertilizable oocyte is produced, ovulation occurs between day 9 and 20 of the menstruation cycle, and the LHRH antagonist is sufficient to suppress LH, while FSH secretion is maintained at a natural level and individual estrogen development is not affected, wherein the dosage of LHRH antagonist 3 mg per dose and is administered by subcutaneous injection, wherein the LHRH antagonist is administered starting cycle day 4 – 8 or 6 – 10 and ovulation occurs between day 9 – 16 of the menstruation cycle or wherein ovulation occurs within 6.5 days following administration of a single or second dose of the LHRH antagonist, wherein ovulation occurs without the administration of a hormone or hormone agonist to induce ovulation, or wherein ovulation is induced by administering a hormone or hormone agonist to induce ovulation and the hormone or hormone agonist selected from the group consisting of native LH, recombinant LH, an LHRH agonist and hCG, wherein the LHRH antagonist is Cetrorelix.

Diedrich et al. teach a method comprising administration of hMG each day starting on day 2 of the cycle, followed by daily subcutaneous doses of 3mg of Cetrorelix starting on day 7 of the cycle and continued until induction of ovulation was achieved with the administration of 10,000 IU of hCG. (See p. 789, left column under Ovarian stimulation for IVF and right column, Figure 2 for a schematic of treatment

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regimen). The method steps recited in the claims are the substantially the same as those taught by Diedrich et al. The claims recite additional limitations in the form of effects of the treatment, such as "wherein follicular growth occurs in the absence of an LH surge, a fertilizable oocyte is produced, ovulation occurs between day 9 and 20 (or day 9 – 16) of the menstruation cycle, and the LHRH antagonist is sufficient to suppress LH, while FSH secretion is maintained at a natural level and individual estrogen development is not affected." Because Diedrich et al. teach the same method steps to the identical patient population (women undergoing ART), the effects that are recited in the claims would by necessity also be achieved by the method taught by Diedrich et al. Note MPEP 2112, I. "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition [or method] patentably new to the discoverer."

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory

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double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 38-39, 42, 45-52, 56-62, 65, 67-74, 78-82, 86-92, 94-100, 102-108, 110-116 and 118-128 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22, 26-42 of copending Application No. 10/661,780. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons. The claims in the instant application are drawn to a method comprising (a) administering an exogenous gonadotropin to induce follicle growth, and (b) administering an LHRH antagonist to prevent a premature LH surge, wherein the LHRH antagonist is administered in a single or dual dosage regimen of 1 to 10 mg per dose, or alternatively the LHRH antagonist is administered in the range of 2-6 mg per dose or alternatively at a dose of 0.25 administered for multiple days and is administered by subcutaneous injection, wherein the LHRH antagonist is administered beginning on menstruation cycle day 1 to 9 (i.e., cycle day) cycle day 4 – 8 or 6 – 10, wherein the LHRH antagonist is Cetrorelix and wherein ovulation is induced by administering a hormone or hormone agonist selected from the group consisting of native LH, recombinant LH, an LHRH agonist and hCG. The claims of the '780 application are drawn to a method comprising administering an LHRH-antagonist such as Cetrorelix, and hMG or recombinant FSH in combination with clomiphene, wherein treatment commences on day 2 after spontaneous menstrual bleeding (i.e., day 2 of cycle) by administering 100 mg clomiphene per day for 3 to 7

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days and 0.2 to 1.0 mg or 0.1 and 5 mg Cetorelix is administered with hMG starting on stimulation day 5 or on day 4 – 9, wherein the LHRH antagonist is administered as a single or dual subcutaneous dose in an amount between 1 – 10 mg or 2 – 6 mg or an initial single dose in the range of 1 mg to 10 mg or 2 – 6 mg followed by a multiple daily dose in an amount between 0.2 and 1.0 mg and ovulation is induced by recombinant LH, native LHRH or hCG. First, the instant claims are written using the open phrase “comprising” thus the additional step in the ‘780 claims reciting administration of clomiphene is encompassed by the instant claims. Second, both the LHRH antagonist (Cetorelix) and the ranges of doses and days in which dosing is to occur recited in the ‘780 application are encompassed by the instant claims. For these reasons, the instant claims are not distinguished over those in the ‘780 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Borgeest whose telephone number is 571-272-4482. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, Ph.D. can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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